DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 10, 2014

Ascension Orthopedics
% Mr. Steven Brown
IMDS
560 West Golf Course Road
Providence, Utah 84332

Re: K140463
Trade/Device Name: Integra External Fixation System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: KTT
Dated: September 12, 2014
Received: September 15, 2014

Dear Mr. Brown:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins -S

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 3: INDICATIONS FOR USE

510(k) Number (if known): K140463

Device Name: Integra External Fixation System

Indications for Use:

INDICATIONS FOR USE

The Integra External Fixation System is an external fixation device intended for use in the treatment of bone conditions including leg lengthening, osteotomies, arthrodesis, fracture fixation, and other bone conditions amenable to treatment by use of the external fixation modality. Additional indications for the Integra External Fixation System include:

- Correction of deformity
- Revision procedures where other treatments or devices have been unsuccessful
- Bone reconstruction procedures
- Fusions and replantations of the foot
- Charcot reconstruction and Lisfranc dislocations
- Ankle distraction (arthrodiastasis)

Prescription Use___X__ AND/OR Over-the-Counter Use _____

(21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Section 4: 510(k) SUMMARY

Device Trade Name: Integra External Fixation System

Date: October 1, 2014

Sponsor: Integra LifeSciences Corporation

Contact Person:
Integra Life Sciences Corp
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Director, Regulatory Affairs
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Manufacturer:
Ascension Orthopedics
8700 Cameron Road, Suite 100
Austin, TX 78754
609-936-3630
frederic.testa@integralife.com

Common Name:	External Fixation Device
Device Classification:	Class II
Classification Name:	Single/multiple component metallic bone fixation appliances and accessories (21 CFR 888.3030)
Regulation:	21 CFR 888.3030, Single/multiple component metallic bone fixation appliances and accessories
Device Regulation Panel:	Orthopedic
Device Product Code:	Orthopedic KTT

Device Description:
The Integra® External Fixation System is a single-use modular external fixator consisting of the following components: rings, foot plates, compression/distraction struts, half-pin bone screws, straight/olive wires, rods, nuts, bolts, clamps, and other modular fixator components. Special instruments (e.g. wrenches) are required for proper assembly of the apparatus. Adjustment of the fixator is possible during the course of treatment. When properly used by an experienced clinician, the Integra External Fixation System may preserve limb function by minimizing operative trauma to anatomical structures and preserving blood supply.

Implants:

Half-pin Bone Screws

The self-drilling half-pin bone screw is 200mm in length and offered in the following sizes: 4mm diameter w/ 20mm thread length, 4mm diameter w/ 30mm thread length, 4mm diameter w/ 40mm thread length, 5mm diameter w/ 30mm thread length, 5mm diameter w/ 40mm thread length, 5mm diameter w/ 50mm thread length, 6mm diameter w/ 30mm thread length, 6mm diameter w/ 40mm thread length, and 6mm diameter w/ 50mm thread length.

K-wires

The wires are offered in the following sizes: 400mm smooth, 400mm olive, and 530mm olive.
K-wire washer in 1 size

Single Use Components:

Rings

Full Ring– The full ring is offered in the following sizes: 140mm, 160mm, 180mm, and 200mm.
Half Ring– The half ring is offered in the following sizes: 140mm, 160mm, 180mm, 200mm, and 220mm.
5/8" Ring– The 5/8" ring is offered in the following sizes: 140mm, 160mm, 180mm, 200mm, and 220mm.
Cross bar – Two lengths

Foot Plates

The foot plate is offered in the following sizes: 140mm, 160mm, and 180mm.

Struts

Struts are offered in the following lengths: long (180-230mm), medium (140-180mm), and short (95-140mm).

Rocker bottom
K-wire holding bolts
Half pin clamps
Extensions:

Threaded rods (20mm through 200mm, hex posts (20mm through 60mm), cubes (1, 2, 3, and 4 hole)

Miscellaneous components:

Washers, nuts, bolts (10mm through 18mm), universal joint, slotted posts (small and large), and plates (straight and twisted).

Reusable Instruments:

Wire tensioner
Wrenches
Wire cutters
Wire Benders
AO adapters
Holding and alignment Blocks
Drill guide assembly
Drills
Provisional Alignment Guides

Materials:

The implants in the Integra External Fixation system are half-pin bone screws and wires and are manufactured from 316L ASTM F138 stainless steel. The rings and footplates are manufactured from anodized aluminum alloy. The wire/half-pin bone screw stopper coin is manufactured from silicone rubber. The rockerbottom frame component is manufactured from Radel plastic, aluminum, and silicone rubber. The reusable instrumentation is manufactured from biocompatible materials, including stainless steel, aluminum, and carbide tips.

Intended Use:

The Integra® External Fixation System is a single-use modular external fixator consisting of rings, half-pin bone screws, wires, and struts and is intended for the treatment of bone conditions including leg lengthening, osteotomies, arthrodesis, fracture fixation, and other bone conditions amenable to treatment by use of external fixation.

Indications for Use:

The Integra External Fixation System is an external fixation device intended for use in the treatment of bone conditions including leg lengthening, osteotomies, arthrodesis, fracture fixation, and other bone conditions amenable to treatment by use of the external fixation modality. Additional indications for the Integra External Fixation System include:

- Correction of deformity
- Revision procedures where other treatments or devices have been unsuccessful
- Bone reconstruction procedures
- Fusions and replantations of the foot
- Charcot reconstruction and Lisfranc dislocations
- Ankle distraction (arthrodiastasis)

Technological Characteristics:

There are no technological characteristics that raise new issues of safety or effectiveness.

Assessment of performance data:

The performance of the Integra External Fixation System was verified to be statistically equivalent to that of the predicate device. The predicate construct and Integra External Fixation System construct were tested both dynamically and statically. The stiffness of the 2 systems was

compared and was statistically equivalent. A summary of the objective, acceptance criteria, results, and conclusions, as well as the detailed test reports can be found in Section 36.

Legally Marketed Predicate Device:
Biomet® Vision™ FootRing™ System (K093057)

Predicate Indications for Use:
The Biomet® Vision™ FootRing™ System (K093057) is indicated for

1. Leg lengthening;
2. Osteotomies;
3. Joint arthrodesis;
4. Fracture fixations;
5. Other bone conditions amenable to treatment by the use of external fixation treatment modality;
6. Correction of deformity;
7. Revision procedure where other treatments or devices have been unsuccessful;
8. Bone reconstruction procedures;
9. Fusions and replantations of the foot
10. Charcot foot reconstruction and Lisfranc dislocation;
11. Ankle distraction (arthrodastasis);

Purpose:
The purpose of this Traditional 510(k) submission is to gain clearance for the Integra External Fixation System.

Based upon the similarities of the Integra External Fixation System and the predicate devices studied, the safety and effectiveness of the Integra External Fixation System is substantially equivalent to the predicate devices referenced.